February 8, 2021

NexGen Medical Systems, Inc.
Craig Pagan
Regulatory Affairs
1050 W. Nasa Blvd.
Suite 136
Melbourne, Florida 32901

Re: K110315
Trade/Device Name: NexGen Peripheral Mechanical Retrieval Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW

Dear Craig Pagan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 20, 2011. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.02.08 07:59:58 -05'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 0 2011

NexGen Medical Systems, Inc.
c/o Mr. Craig Pagan
1050 W. NASA Blvd., Suite 136
Melbourne, FL 32901

Re: K110315
Trade Name: NexGen Peripheral Mechanical Retrieval Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: September 27, 2011
Received: September 28, 2011

Dear Mr. Pagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K110315

Device Name: NexGen Peripheral Mechanical Retrieval Device

INDICATIONS:

The NexGen Mechanical Retrieval Device (MRD) is indicated for the removal of embolic / thrombotic material, including thrombus and debris, from peripheral arteries and veins, peripheral bypass grafts, and the removal of thrombus from clotted synthetic dialysis grafts and arterio-venous fistulas.

CONTRAINDICATIONS:

- Not intended for peripheral vasculature dilatation.
- Not for coronary or neurovascular use.
- Not intended for the removal of fibrous or calcified material.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110315

510(K) SUMMARY

OCT 2 0 2011

510(k) Number: K110315

Date Prepared October 20, 2011

Submitter Information

Submitter's Name:	NexGen medical Systems Inc.
Address:	10471 Double R Blvd. Suite A Reno, NV 89521
Establishment Registration	3008106780
Contact Person:	John Kucharczyk Phone: (775) 851-7337 Fax: (775) 849-4162 Email: johnkucharczyk@aol.com

Device Information

Trade Name	NexGen Peripheral Mechanical Retrieval Device (MRD)
Common Name	Embolectomy Catheter
Classification Name	Embolectomy Catheter
Product Code:	DXE
Regulation:	Class II, 21 CFR 870.5150

Predicate Devices

K090932	NexGen Medical Systems – NexGen Peripheral Mechanical Retrieval Device (MRD)
510(k) Unknown	Edwards Lifesciences - Fogarty Venous Thrombectomy Catheter
K892410	Edwards Lifesciences - Fogarty Thru Lumen Embolectomy Catheter
K070403	Vascular Solutions - Pronto .035" extraction catheter

Device Description

The MRD is a member of a family of sterile, single use, catheter-based devices that are intended to mechanically remove blood clots and other obstructions from blood vessels in the human body. The MRD is designed to be used for peripheral vascular applications.

The Device design is intended to allow easier access into anatomically difficult endovascular locations because it is pushed out of a small profile guide catheter. Other devices such as those delivering laser, ultrasound, or photo-acoustical energy may be too stiff to access tortuous blood vessels, and too large.

The MRD consists of a stainless steel coil that is inserted into a standard 4F guide catheter. The guide catheter is inserted into the vessel and past the occlusion using a standard guide catheter. Coils released from the MRD are then deployed distal to the occlusion. As the guide catheter is withdrawn, additional MRD coils are released proximal to the occlusion, thereby enmeshing the embolic material for removal.

Intended Use/Indications for Use

The NexGen Mechanical Retrieval Device (MRD) is indicated for the removal of embolic / thrombotic material, including thrombus and debris, from peripheral arteries and veins, peripheral bypass grafts, and the removal of thrombus from clotted synthetic dialysis grafts and arterio-venous fistulas.

Contraindications:

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Summary of Non-Clinical Testing

Performance Testing:
The following bench testing was conducted to verify the device met design specifications and its intended use:

- Simulated Use and Efficacy Test
- Pushability/Trackability Testing
- In-Vitro Emboli Testing
- Joint Tensile Strength Test
- Tip Flexibility
- Corrosion Resistance
- Torque Testing
- Kink Diameter Testing
- Radial Force Testing
- Bypass Graft Testing

Biocompatibility:
Biocompatibility testing has been performed in accordance with ISO 10993, "Biological Evaluation of Medical Devices". The materials used in the NexGen Peripheral Mechanical Retrieval Device (MRD) have demonstrated that they are biocompatible.

Summary of Clinical Testing

No clinical evaluations of this product have been conducted

Statement of Equivalence

Based on the information and data presented, NexGen Medical Systems, Inc. considers the NexGen modified Peripheral Mechanical Retrieval Device (MRD) to be substantially equivalent to the NexGen Peripheral Mechanical Retrieval Device (MRD), NexGen

Medical Systems; Fogarty Venous Thrombectomy Catheter and Fogarty Thru Lumen Embolectomy Catheter, Edwards Lifesciences; and the Pronto .035" Extraction Catheter, Vascular Solutions, Inc. The testing performed confirms that the NexGen modified Mechanical Retrieval Device (MRD) will perform as intended.

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Bram D. Zuckerman, M.D.
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